REMARKS

Claims 124-149 are pending. Claims 137-149 are withdrawn from consideration, by the Examiner. Upon entry of the foregoing amendments, claims 124-136 are under examination. Claims 124 and 132 are amended. No new terms have been added to the claims.

Applicants respectfully request withdrawal of the rejections, in light of the foregoing amendments and the following remarks.

Response to Arguments:

The Examiner has rejected the arguments, filed on September 18, 2002, regarding Hyon in view of Howard and in further view of Bashir. The examiner states that applicants have not claimed "how the melting melts are produced" and "any specific crystallinity effects in the independent claims." In response, applicants, amend independent claims 124 and 132, reciting that the multiple melting peaks are "a result of irradiation-generated heat, which reduces crystallinity of the ultra high molecular weight polyethylene." The amended claims are supported by specification (see for example, page 70, last paragraph and page 71, Table 20), therefore, no new matter is added. Therefore, withdrawal of rejections is solicited.

Claim Rejections:

Anticipation Rejections

On page 3 of the Office Action, the Examiner has rejected the claims 124-127, 129-130 and 132-135 as allegedly being anticipated by McKellop *et al.* Applicants

respectfully disagree with the Examiner and note that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference that has an earlier date than the application. See Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131. Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01. Claims are to be given their broadest reasonable interpretation consistent with Applicants' specification. See In re Zletz, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow); MPEP § 2111.

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See Akzo, N.V. v. U.S.I.T.C., 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); In re Brown, 141 USPQ 245, 249 (CCPA 1964).

Applicants provide following arguments to overcome the 35 USC § 102 rejections:

McKellop is not a prior art

Applicants refer to the priority section, on page 1, 1st paragraph, of the application and point out that the instant application claims priority to U.S. Application Serial No. 08/726,313 (filed October 2, 1996), which antedates McKellop's filing date (see chart below). Therefore, McKellop *et al.* is not a prior art to instant application. Thus, the rejection is improper and withdrawal is solicited.

Chart: Support for Terms Used in the Claims

Amended Independent Claims	Exemplary Support in Application Serial No. 08/726,313; Filed October 2, 1996
Claim 124. A medical prosthesis for use within a body, said prosthesis being formed of radiation treated ultra high molecular weight polyethylene having cross-links and multiple melting peaks, wherein the multiple melting peaks are a result of irradiation-generated heat, thereby reducing crystallinity of the ultra high molecular weight polyethylene.	"medical prosthesis for use within a body": page 6, lines 10-13. "radiation treated ultra high molecular weight polyethylene": page 2, lines 11-12. "cross-links": page 3, lines 1-7; page 51, lines 14-18, claims 12-13. "multiple melting peaks": page 43, lines 8-10; page 44, lines 1-6, Table 11. "irradiation-generated heat": page 15, lines 15-28. "reducing crystallinity": Figure 4.
Claim 132. Radiation treated ultra high molecular weight polyethylene having multiple melting peaks and cross-links, wherein the multiple melting peaks are a result of irradiation-generated heat, thereby reducing crystallinity of the ultra high molecular weight polyethylene.	"radiation treated ultra high molecular weight polyethylene": page 2, lines 11-12. "multiple melting peaks": page 43, lines 8-10; page 44, lines 1-6, Table 11. "cross-links": page 3, lines 1-7; page 51, lines 14-18, claims 12-13. "irradiation-generated heat": page 15, lines 15-28. "reducing crystallinity": Figure 4.

McKellop does not teach the invention

Applicants further state that the Examiner has misinterpreted McKellop's Figs. 3, 14, 15, and the corresponding description at col. 12, lines 37-50; and explain that: McKellop does not disclose "UHMWPE specimens" having "multiple melting peaks" in Figs. 3, 14, and 15. Rather, McKellop discloses "UHMWPE specimens" showing "a gradient in melting temperature" that is formed through the gradient of crosslinking in

the bulk of the UHMWPE, in other words, having a continually changing melting temperature, unlike the instant invention of having "multiple melting peaks" throughout the polyethylene. Thus, the Examiner has failed to demonstrate that each and every claim term is contained in a single prior art reference. Therefore, claims 124-127, 129-130 and 132-135 are not anticipated by McKellop *et al.* and withdrawal of the rejections is requested.

For further clarity, Applicants amend claims 124 and 132 by more clearly describing the process of producing multiple melting peaks by irradiation-generated heat. Applicants respectfully request the withdrawal of the rejections.

Obviousness Rejections

On pages 4-9, of the Office Action, the Examiner rejected claims 124, 127-132 and 135-136 as allegedly being obvious over Saum *et al.* in view of Lemstra. Applicants respectfully disagree with the Examiner and provide following arguments to overcome the 35 USC § 103 rejections:

Saum is not a prior art

Applicants refer to the priority section, on page 1, 1st paragraph, of the application and point out that the instant application claims priority to application U.S. Serial No. 08/726,313, filed October 2, 1996. Saum claims priority to Provisional Application No. 60/027,354, filed October 2, 1996, which does not antedate the priority date of the instant application. See the chart set forth above. Therefore, Saum *et al.* is not a prior art to the instant application.

As indicated above, Saum *et al.* is not a prior art to instant application, thus, any combination with Saum *et al.* is improper.

Saum does not teach or suggest the present invention

At the outset, applicants note that the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* MPEP §§ 2142-43 (August 2001). Thus, the examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs or unknown authority. *See In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). *See U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants submit that the rejections do not meet this test, as explained below:

Saum *et al.* describes heating of UHMWPE at column 2, lines 50-61. The heating process disclosed in Saum is not the irradiation, but is simply by heating before

or after irradiation, which means by putting the UHMWPE in an oven to heat. Therefore the combination of Saum *et al.* and Lemstra will not make the instant invention obvious.

Lemstra does not teach the invention

Applicants state that the Examiner has misinterpreted Lemstra's Fig. 3 and the corresponding description at col. 21, lines 7-20; and explain that: Lemstra does not disclose "irradiation to form multiple melting peaks." Applicants refer to Lemstra's col. 20, lines 55-60, for a clear description of FIG. 3, which shows a "comparative DSC melting curve". The melting peaks of Lemstra were generated by heating during DSC and not by irradiation. Therefore the combination of Lemstra and Saum *et al.* will not make the instant invention obvious.

In view of the above arguments, it is clear that the Examiner has not set forth a *prima facie* case of obviousness. Withdrawal thereof is respectfully requested.

CONCLUSION

In view of this Amendment and Applicants' remarks above, Applicants respectfully submit that the application is in condition for allowance. If any additional fees or additional extensions of time are required with the filing of this Amendment, Applicants respectfully request such fees and extensions be charged to Deposit Account No. 08-1641.

Respectfully submitted,

4-29-03

Date

John P. Isacson
Reg. No. 33,715

Customer ID No. 26633
HELLER EHRMAN WHITE & MCAULIFFE
1666 K Street, NW, Suite 300
Washington, DC 20006
Phone: (202) 912-2000
Fax: (202) 912-2020